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**PATENT**

Atty. Docket No.  
AR02366USACON3

Date: August 20, 2003 By:   
Lois E. Miller

**CN 27777**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants:	George GUITTARD et al.	Art Unit:	to be assigned
Serial No.:	herewith	Examiner:	not yet assigned
Filed:	herewith		
For:	METHOD FOR MANAGEMENT OF INCONTINENCE		

Mail Stop: Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750 the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750 the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of references **BK-BZ** and **CB-CF** listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of the following references listed on the attached Form PTO-1449 are **NOT** enclosed herewith:

☐ In view of the voluminous nature of references \_\_\_\_\_, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☒ Copies of references **AA-BJ** and **CA** are not provided because they were previously cited or submitted to the Office in prior applications:

USSN: 09/785,805, filed 02/16/01, (pending);

USSN: 09/280,309, filed 03/29/99, (Now Patent 6,262,115);

USSN: 08/806,773, filed 02/26/97 (Now Patent 5,912,268);

USSN: 08/706,576, filed 09/05/96 (Now Patent 5,840,754);

USSN: 08/445,849, filed 05/22/95 (Now Patent 5,674,895).

☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:


☒ Attached are copies of PCT Search Reports from corresponding PCT applications PCT/US96/06639 and PCT/IB98/01982.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,

Dated: August 19, 2003  
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Enclosures:

1. PTO FORM 1449 (3 sheets)
2. PCT Search Report dated August 13, 1996 (3 pages);
3. PCT Search Report dated April 28, 1999 (3 pages);
4. References **BK – BZ** and **CB – CF** (21 references).

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: <b>AR02366USACON3</b>	SERIAL NO.: <b>TO BE ASSIGNED</b>	
<b>INFORMATION DISCLOSURE STATEMENT FOR PATENT</b> <i>(Use several sheets if necessary)</i>				APPLICANT: <b>George GUITTARD, et al.</b>		
				FILING DATE: <b>Herewith</b>	GROUP: <b>to be assigned</b>	
<b>U.S. PATENT DOCUMENTS</b>						
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
AA	6,262,115	07/17/01	GUITTARD <i>et al.</i>			
AB	6,124,355	09/26/00	GUITTARD <i>et al.</i>			
AC	5,912,268	06/15/99	GUITTARD <i>et al.</i>			
AD	5,840,754	11/24/98	GUITTARD <i>et al.</i>			
AE	5,811,126	09/22/98	KRISHNAMURTHY			
AF	5,674,895	10/07/97	GUITTARD <i>et al.</i>			
AG	5,399,359	03/21/95	BAICHWAL			
AH	4,902,514	02/20/90	BARCLAY <i>et al.</i>			
AI	4,863,456	09/05/89	STEPHENS <i>et al.</i>			
AJ	4,853,229	08/01/89	THEEUWES			
AK	4,824,675	04/25/89	WONG <i>et al.</i>			
AL	4,816,263	03/28/89	AYER <i>et al.</i>			
AM	4,783,337	11/08/88	WONG <i>et al.</i>			
AN	4,752,470	06/21/88	MEHTA			
AO	4,721,613	01/26/88	URQUHART <i>et al.</i>			
AP	4,612,008	09/16/86	WONG <i>et al.</i>			
AQ	4,434,153	02/28/84	URQUHART <i>et al.</i>			
AR	4,327,725	05/04/82	CORTESE <i>et al.</i>			
AS	4,285,987	08/25/81	AYER <i>et al.</i>			
AT	4,200,098	04/29/80	AYER <i>et al.</i>			
AU	4,111,202	09/05/78	THEEUWES			
AV	4,093,709	06/06/78	CHOI <i>et al.</i>			
AW	4,088,864	05/09/78	THEEUWES <i>et al.</i>			
AX	4,083,949	04/11/78	BENEDIKT			
AY	4,079,038	03/14/78	CHOI <i>et al.</i>			
AZ	4,070,347	01/24/78	SCHMITT			
BA	4,066,747	01/03/78	CAPOZZA			
BB	4,063,064	12/13/77	SAUNDERS <i>et al.</i>			
BC	3,992,518	11/16/76	CHEIN <i>et al.</i>			
EXAMINER			DATE CONSIDERED			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

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INFORMATION DISCLOSURE STATEMENT FOR PATENT  (Use several sheets if necessary)				APPLICANT: <b>George GUITTARD, et al.</b>	
				FILING DATE: <b>Herewith</b>	GROUP: <b>to be assigned</b>
<b>U.S. PATENT DOCUMENTS</b>					
	<b>BD</b>	3,962,414	06/08/76	MICHAELS	
	<b>BE</b>	3,916,899	11/04/75	THEEUWES <i>et al.</i>	
	<b>BF</b>	3,845,770	11/05/74	THEEUWES <i>et al.</i>	
	<b>BG</b>	3,811,444	05/21/74	HELLER <i>et al.</i>	
	<b>BH</b>	3,139,383	06/30/64	NEVILLE	
	<b>BI</b>	2,996,431	08/16/61	BARRY	
	<b>BJ</b>	2,799,242	07/16/57	WURSTER	
<b>FOREIGN PATENT DOCUMENTS</b>					
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS
					SUB- CLASS
					TRANSLATION YES NO
	<b>BK</b>	WO 96/37202	11/28/96	PCT	
	<b>BL</b>	WO 96/12477	05/02/96	PCT	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>					
	<b>BM</b>	Michael M. Coleman, et al., <u>Polymer</u> , 31:1187-1231, July 1990. "A Practical Guide to Polymer Miscibility"			
	<b>BN</b>	KODAMA KK, <u>DATABASE WPI</u> , AN: 94-068306, Derwent Publications Ltd., Jan. 18, 1994. "Sustained release preparation of oxybutynin chloride - comprises oxybutynin chloride, acidic substance, gelling agent and higher alcohol"			
	<b>BO</b>	KODAMA KK, <u>DATABASE WPI</u> , AN: 94-031722, Derwent Publications Ltd., Dec. 21, 1993. "Pharmaceutical preparations for prolonged action against urinary incontinence - comprise sustained release oxybutynin chloride for pharmaceutical compsn. sustained release coating film of non water soluble polymers and/or ethylcellulose"			
	<b>BP</b>	Enomoto, et al., <u>Chemical Abstracts</u> , 120(18):227011, May 2, 1994. "Sustained release preparation of oxybutynin chloride"			
	<b>BQ</b>	Enomoto, et al., <u>Chemical Abstracts</u> , 120(14):173499, April 4, 1994. "Sustained release formulations containing oxybutynin chloride"			
	<b>BR</b>	Julian H. Fincher, <u>J. Pharm Sci.</u> , 57(11):1825-1835, November 1968. "Particle Size of Drugs and Its Relationship to Absorption and Activity"			
	<b>BS</b>	P. Grafton, <u>Modern Plastics Encyclopedia</u> , 46:62-70, 1969. "General principles for designing with plastics"			
	<b>BT</b>	Suneel K. Gupta, et al., <u>Clinical Pharmacology &amp; Therapeutics</u> , 61(2):Abstract PIV-26, 1997. "Evidence of Site Specific Presystemic Metabolism of Oxybutynin Following Oral Administration"			
	<b>BU</b>	K.W. Leong & R. Langer, et al., <u>Advanced Drug Delivery Reviews</u> , 1:199-233, 1987. "Polymeric controlled drug delivery"			
	<b>BV</b>	Robert J. Linhardt, <u>Controlled Release of Drugs: Polymers and Aggregate Systems</u> , Ch.2, pp.53-95, 1989. "Biodegradable Polymers for Controlled Release of Drugs"			
EXAMINER				DATE CONSIDERED	
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<b>OTHER DOCUMENTS</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>					
	<b>BW</b>	S.M. Lu & Jun-Ying Yu, <u>Inter. J. Pharm.</u> , 112:117-124, 1994. "Dimensionless Presentation for Drug Release from a Coated Pure Drug Bead: 2 Experiment,"			
	<b>BX</b>	Carl Gustaf Nilsson, et al., <u>Neurourology and Urodynamics</u> , 16(6):533 542, 1997. "Comparison of a 10-mg Controlled Release Oxybutynin Tablet with a 5-mg Oxybutynin Tablet in Urge Incontinent Patients"			
	<b>BY</b>	<u>Remington's Pharmaceutical Sciences</u> , 14 <sup>th</sup> Edition, Ch.86 "Powders", pp 1626-1648, Mack Publishing Company, Easton, PA 1970.			
	<b>BZ</b>	<u>Remington's Pharmaceutical Sciences</u> , 17 <sup>th</sup> Ed., Ch 35, "Dissolution", pp 653-666, and Ch. 90, "Oral Solid Dosage Forms", pp. 1603-1625; Mack Publishing Company, Easton, PA 1985			
	<b>CA</b>	Roerdink, et al., <u>Drug Carrier Systems</u> , 9:57-109, 1989.			
	<b>CB</b>	W.J. Roff et al., <u>Handbook of Common Polymers</u> , CRC Press, Cleveland Ohio, 1971.			
	<b>CC</b>	<u>The United States Pharmacopia - The National Formulary</u> , USP23:NF18, pp. 1791-1796, 1995. "<711> Dissolution"			
	<b>CD</b>	<u>The United States Pharmacopia - The National Formulary</u> , USP XXII / NF XVII, pp. 1578-1579, 1990. "<711> Dissolution"			
	<b>CE</b>	Dale E. Wurster, <u>J. Am. Pharm. Assoc</u> , 48(8):451-454, August 1959. "Air-Suspension Technique of Coating Drug Particles"			
	<b>CF</b>	Dale E. Wurster, <u>J. Am. Pharm. Assoc</u> , 49(2):82-84, February 1960. "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II"			
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